

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 14 FEB 2006

WIPO

PCT

Applicant's or agent's file reference BW40F		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IT2004/000643		International filing date (day/month/year) 23.11.2004	Priority date (day/month/year) 03.12.2003	
International Patent Classification (IPC) or national classification and IPC A61F13/36				
Applicant MICRO TECH S.R.L. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 3 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 29.09.2005		Date of completion of this report 13.02.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Hamann, J Telephone No. +49 89 2399-7046 		

BEST AVAILABLE COPY

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IT2004/000643

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-7 as originally filed

Claims, Numbers

1-12 received on 29.09.2005 with letter of 28.09.2005

Drawings, Sheets

1/2, 2/2 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/T2004/000643

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-5,7-12
	No: Claims	1,6
Inventive step (IS)	Yes: Claims	2-5,8,9,11,12
	No: Claims	1,6,7,10
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

REST AVAILABLE COPY

INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)

International application No.

PCT/IT2004/000643

Re Item V.

- 1 Reference is made to the following documents:
D1 : US 5,203,767 A (CLOYD ET AL) 20 April 1993 (1993-04-20)
D2 : US 3,698,393 A (CHARLES E. STONE) 17 October 1972 (1972-10-17)
D3 : US 5,310,407 A (CASALE ET AL) 10 May 1994 (1994-05-10)
- 2 The application does not meet the requirements of Article 6 PCT, because **claims 1 and 10 are not clear.**
 - 2.1 In claims 1 and 10 it is not clear whether the plug radio-opaque location means forms part of the subject-matter of the claim.
 - 2.2 The sizes of the plug and the plug radio-opaque location means according to claim 10 are defined with reference to a tubular body which is neither part of the subject-matter of the claim nor standardised (PCT-Guidelines 5.37).
- 3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1 and 6 is not new** in the sense of Article 33(2) PCT.
Document **D1** discloses an endoscopic surgery device according to these claims with:
absorbing plug: gauze peanut 22
tubular body: trocar 16
plunger: forceps 38
radio-opaque location means: **tether 24, column 2, lines 51-54** (not disc 26 or ring 32)
gripping means: jaws of forceps 38
The forceps 38 is suitable for pushing ~~the~~ **gauze** peanut 22 outside of the trocar and for gripping the tether 24.
- 4 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of **claims 7 and 10 does not involve an inventive step** in the sense

of Article 33(3)PCT:

- 4.1 Providing the trocar 16 of document **D1** with ring type handle means, and thereby arriving at the subject-matter of **claim 7**, is just a design option.
- 4.2 Since the dimensions of the tubular body in independent **claim 10** are arbitrary, the subject-matter of this claim differs from the disclosure of **D2** (or most of the other documents cited in the International Search Report) only in that the absorbing plug has haemostatic properties. An absorbing plug with haemostatic properties, however, is known from document **D3** (see column 3, lines 44-46):

- 8 -

CLAIMS

1. An endoscopic surgery device for the removal of organic fluids from a body cavity, comprising an absorbing plug (8) and a tubular body (1), suitable for slidingly housing said plug (8), and a plunger (4) slidingly engageable in said tubular body to push said plug outside thereof and place it at the surgical site, said tubular body (1) and plunger (4) having distal ends (1a, 4a) and proximal end (1b, 4b), characterised in that said plug is connected to plug radio-opaque location means (9,10) floating in relation to the internal organs, blood or other liquids present at the surgical site, said location means having a size such as to let them pass through said tubular body, and that at the distal end (4a) of said plunger (4) means (5) are provided for gripping said location means to recover said plug after use by retracting it inside said tubular body.

2. Device according to claim 1, wherein said location means comprise at least one ball (10) of lower specific weight than that of the internal organs, blood or other liquid present at the surgical site, connected to said plug (8) by a wire (9).

3. Device according to claim 2, wherein said at least one ball (10) has smaller dimensions than the internal ones of said tubular body (1).

4. Device according to any one of the previous claims, wherein said plunger comprises a stem (4) and said gripping means comprises a loop (5) at the distal end (4a) of said stem (4), said loop being wider than said ball (10).

5. Device according to claim 4, wherein said loop (5) is formed by a thin plate bent and connected by its ends to

BEST AVAILABLE COPY

the distal end of said stem.

6. Device according to any one of the previous claims, wherein at the proximal ends (1b, 4b) of said tubular body (1) and of said stem (4) handle means (3a, 3b, 7) are provided for actuating axial sliding of said stem in one direction or the other as a result of corresponding pressure actions exerted simultaneously in opposite directions on said handle means.

7. Device according to claim 6, wherein said handle means are of the ring type to allow engaging of the fingers of a user.

8. Device according to claim 7, wherein at the proximal end (1b) of said tubular body (1) a pair of handle rings (3a, 3b) are provided, diametrically opposite and co-planar thereto, while at the proximal end (4b) of said stem (4) an handle ring (7) is provided, co-planar thereto.

9. Device according to any one of the previous claims, wherein the ball surface is white or coloured with a light colour.

10. Organic liquid absorbing plug for surgical use comprising an elongated body in a material with absorbent and haemostatic properties suitable for being placed at a surgical site in a body cavity through a tubular body and characterised in that said elongated body is connected to plug radio-opaque location means (9, 10), floating in relation to the internal organs, blood or other liquids present at the surgical site, said location means having a size such as to let them pass through said tubular body.

11. Organic liquid absorbing plug according to claim 10, wherein said location means comprise at least one ball (10) with lower specific weight than that of internal

BEST AVAILABLE COPY

- 10 -

organs, blood or another liquid present at the surgical site, connected to said plug by a wire (9).

12. Organic liquid absorbing plug according to claim 10 or 11, wherein the ball surface is white or coloured with a
5 light colour.

BEST AVAILABLE COPY